REMARKS/ARGUMENTS

The preceding amendments and following remarks are submitted in response to the non-final Office Action mailed June 15, 2005, setting a three month shortened statutory response ending September 15, 2005. Claims 4-5 and 10-12 remain pending in this application. Reconsideration, examination and allowance of all pending claims are respectfully requested.

35 U.S.C. § 102(b) Rejections

In paragraph 2 of the Office Action, the Examiner rejected claims 4, 10, and 12 under 35 U.S.C. § 102(b) as being anticipated by *Wolinsky et al.* (U.S. Patent No. 5,087,244). Applicants respectfully traverse this rejection.

The *Wolinsky et al.* reference appears to suggest a catheter for delivering chemotherapeutic agents at a controlled rate to the arterial wall of an artery. As can be seen in Figure 2, the catheter can include a catheter shaft (12) having an inflation lumen (18) that terminates at an opening (20) into the interior of a balloon (16), and a guidewire lumen (26) adapted to receive a guidewire (27). A number of holes (29) formed through the wall of the balloon (16) permit the delivery of a therapeutic agent such as heparin to the arterial wall, causing the therapeutic agent to penetrate into the localized tissue.

In contrast to *Wolinsky et al.*, claim 4 of the Application recites a balloon angioplasty catheter including, among other novel elements, a balloon including an inflatable envelope portion, and a tubular member defining a perfusion lumen extending through the balloon and decreasing distally in cross section within the inflatable envelope portion. Such configuration can be seen, for example, in Figure 28 of the present

Application, which shows a perfusion lumen (117) decreasing distally in cross-section at a region (112) located within the inflatable envelope portion (16).

Unlike the balloon angioplasty catheter recited in claim 4, the inflation lumen (18) in *Wolinsky et al.* does not decrease distally in cross-section within the inflatable envelope portion, but instead appears to terminate abruptly at an opening (20) in which the cross-section increases distally into the inflatable envelope portion of the balloon (16). Such configuration can be clearly seen in Figure 2 of *Wolinsky et al.*, which shows the cross-section increasing distally (*i.e.* to the left) of the opening (20). If, assuming the "perfusion lumen" in *Wolinsky et al.* is interpreted to include both the inflation lumen (18) and the interior of the balloon (16) together, then Applicants further assert that *Wolinsky et al.* fails to disclose or suggest a separate inflatable envelope portion, as further recited in claim 4. Thus, irrespective of either interpretation, Applicants respectfully assert that *Wolinsky et al.* fails to disclose each and every element of claim 4 necessary to support an anticipation rejection.

With respect to the rejection of claims 10-12, Applicants assert that the *Wolinsky et al.* reference fails to disclose or suggest a balloon angioplasty catheter including a second tubular member defining a guidewire lumen that is collapsible, during normal use, in the absence of an inserted guidewire, as recited in claim 10. The *Wolinsky et al.* reference is silent on the configuration of the guidewire lumen (26), stating only that the lumen (26) "may be used to receive a guidewire 27 by which the catheter may be guided through a patient's vasculature to the site to be treated." *See Wolinsky et al.* at col. 3, lines 43-46. As such, the *Wolinsky et al.* reference does not disclose or suggest the

limitation that the guidewire lumen is collapsible, during normal use, in the absence of an inserted guidewire.

Applicants further assert that such collapsible configuration is not an inherent feature in balloon angioplasty catheters, particularly when the catheter shaft described in *Wolinsky et al.* is formed from an extruded plastic material such as polyethylene. *See Id.* at col. 3, lines 25-28. Although the catheter and guidewire lumen of the present invention will likely experience some movement and/or bending as the device is maneuvered through the arteries of the patient, such movement and/or bending does not imply that the guidewire lumen will "collapse", as suggested by the Examiner. Indeed, such assumption would seem to suggest that other elements of the catheter shaft such as the inflation lumen (18) would also "collapse" when the catheter is maneuvered through the patient's body, preventing the device from operating as described.

Accordingly, Applicants submit that *Wolinsky et al.* does not anticipate the balloon angioplasty catheter of claim 10. Additionally, since claim 12 depends from claim 10, and includes additional significant elements, Applicants respectfully submit that claim 12 is not anticipated by *Wolinsky et al.*

In paragraph 3 of the Office Action, the Examiner rejected claims 4-5 under 35 U.S.C. § 102(b) as being anticipated by *Jang* (U.S. Patent No. 4,744,366). The Examiner states that *Jang* discloses an elongated catheter with a balloon and perfusion lumen that extends through the balloon and decreases distally in cross-section within the inflatable envelope portion. Applicants respectfully disagree.

The *Jang* reference appears to suggest several balloon angioplasty catheter configurations each utilizing a number of balloons that can be independently inflated

within a patient's body. In one such embodiment depicted in Figure 1, for example, the balloon angioplasty catheter (10) may include a first balloon (16), a second balloon (20) disposed about the first balloon (16), and a third balloon (42) located distally of the first and second balloons (16,20). Inflation of each of the balloons (16,20,42) is accomplished using a respective inflation lumen (24,26,28), which as shown in Figure 1, terminates within the balloon interior. In some implementations, a set of proximal and distal holes (36,40) in fluid communication with a central lumen (22) can be provided to permit blood to flow past each of the balloons.

Element "12" referred to by the Examiner as a "perfusion lumen" is described and depicted in *Jang* as a catheter shaft that supports each of the inflatable balloons. While the catheter shaft (12) includes several inflation lumens (24,26,28) that deliver fluid to each of the inflatable balloons, none of these lumens (24,26,28) are equivalent to a perfusion lumen decreasing distally in cross section, as recited in claim 4. The only lumen that functions as a perfusion lumen in *Jang* is the central lumen (22) disposed within the catheter shaft (12). However, as can be seen in Figures 2-5, the central lumen (22) does not appear to decrease distally in cross-section within the inflatable envelope portion of the balloons (16,20,42). Accordingly, Applicants respectfully assert that *Jang* does not anticipate claim 4.

Because independent claim 4 is allowable, Applicants further assert that claim 5 is also allowable for the reasons stated above, and since it adds other significant elements to distinguish it from the cited prior art. As no arguments were provided in support of the rejection of dependent claim 5, Applicants respectfully request that the Examiner indicate those passages and/or figures in *Jang* that teach the use of a metallic ribbon coil support.

In paragraph 5 of the Office Action, the Examiner rejected claims 10-12 under 35 U.S.C. § 103(a) as being unpatentable over *Crocker* (U.S. Patent No. 5,522,800), and further in view of *Zeiher* (U.S. Patent No. 5,061,267). The Examiner states that *Crocker* discloses an elongated catheter with a balloon, perfusion lumen, and guidewire lumen as well as a metal ribbon coil support, wherein the perfusion lumen has a smaller cross section at its distal end than its proximal end. The Examiner acknowledges that *Crocker* fails to teach a guidewire lumen that is collapsible, during normal use, in the absence of an inserted guidewire, but states that *Zeiher* discloses such feature. According to the Examiner:

> At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the catheter of Crocker with the guidewire feature of Zeiher because it is well known in the art to use collapsible guidewires when performing medical procedures that involves dilation of an artery since the catheter will need to fit into small openings before dilation. Therefore, if the guidewire lumen collapsed this would save space as shown and taught by Zeiher since this concept of minimizing space is taught in Crocker.

Applicants respectfully assert that it would not have been obvious to combine *Zeiher* with *Crocker* to arrive at the balloon angioplasty recited in claims 10-12 since there is no motivation or suggestion to combine the references. As discussed previously, the *Crocker* reference discloses a catheter (10) including an elongated tubular body (12) having a proximal end (14) and a distal end (16), an inflatable balloon (28), and a movable support (50) that can be manipulated between a proximal, introductory position (Figure 4) to a distal, perfusion position (Figure 6). A number of influent and effluent fluid ports (30,32) are in fluid communication with each other via a central lumen (54), which serves the twofold purpose of carrying perfusion fluid across the site of the balloon (28) as well as receiving the guidewire. In *Crocker*, only the perfusion lumen (54) and

not the guidewire lumen (42) is collapsible. This is apparent from col. 6, lines 56-60 of *Crocker*, which provides:

> Preferably, a stiffening wire or other stiffening structure is positioned within guidewire lumen 42 between the guidewire port and the manifold 18. Such a stiffening wire improves the pushability of the catheter, as will be understood by one of skill in the art.

The *Zeiher* reference, in turn, appears to suggest a balloon catheter including a balloon envelope (1) having a compressible guide hose (2) adapted to receive a guidewire (3), and a coaxial cable (8) that can be used to heat the envelope (1) using microwaves. When the interior (4) of the envelope (1) is charged with liquid under pressure, as shown in Figures 2-3 of *Zeiher*, the guide hose (2) is squeezed flat by the internal pressure, preventing heat-coagulated blood induced by the microwaves from passing through the guide hose (2) in the direction towards the retracted guide wire (3). *See Zeiher* at col. 3, lines 24-30.

Applicants respectfully assert that there would have been no motivation or suggestion to combine the compressible guide hose (2) of *Zeiher* with the guidewire lumen (42) of *Crocker* since such combination would affect the pushability of the balloon angioplasty catheter, as taught by *Crocker*. As discussed above, *Crocker* states that the presence of a stiffening wire or other stiffening structure between the guidewire port and the manifold improves the pushability of the catheter. Thus, *Crocker* specifically teaches away from the use of a guidewire lumen that is collapsible, during normal use, in the absence of an inserted guidewire. While Applicants agree with the Examiner that minimizing space is often an important feature in the design of balloon angioplasty catheters, Applicants assert that the use of "collapsible guidewires" is not well known in the art.

In addition, Applicants assert that there is not motivation or suggestion to combine references since the specific technical problem solved by the compressible guide hose (2) in *Zeiher* is not present in the catheter described by *Crocker*. In *Zeiher*, the compression feature of the guide hose (2) described therein is to prevent heat-coagulated blood caused by the microwaves from flowing in a direction towards the retracted guide wire (3). In *Crocker*, however, the rationale for preventing such blood flow towards the retracted guidewire is not present since the catheter in *Crocker* does not induce heat-coagulation the blood. Indeed, *Crocker* appears to suggest that blood flow through the guidewire lumen is actually desired, stating that influent and effluent ports can be provided for the purpose of carrying perfusion fluid across the site of balloon. As such, Applicants assert that there is no motivation or suggestion to combine *Zeiher* with *Crocker* to arrive at the balloon angioplasty catheter of claim 10. Additionally, since claim 12 depends from claim 10, and includes additional significant elements, Applicants respectfully submit that claim 12 is not unpatentable over *Crocker* in view of *Zeiher*.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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